Docket No: AM101333 Application No: 10/796,925

10/796,925 Patent

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: Wumin LI et al.

Application No.: 10/796,925 Group Art No.: 1645

Filed: March 10, 2004 Examiner: Lakia J. TONGUE

For: ADJUVANTED BOVINE VACCINES
Confirmation No.: 3270

Customer Number: 25291

Mail Stop Appeal Brief Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

# AMENDED REPLY BRIEF UNDER 37 C.F.R. § 41.37 (d)

#### Sir/Madam:

This paper is in response to the Notification of Non-compliant Appeal Brief (37 C.F.R. § 41.37) mailed February 22, 2010, due for response on March 22, 2010.

According to the Notification of Non-Compliant Appeal Brief ("the notification"), the Brief filed on November 2, 2009 was not compliant because the brief did not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal. The notification advises that only the section that was found defective needs to be submitted and not the entire brief.

In this paper, section V, Summary of the Claimed Subject Matter is amended to include the identification of the support, by page and line number, of every means plus function and step plus function of each independent claim involved in the appeal. The basis for finding the Appeal Brief non-compliant is thus believed to be addressed and overcome. Pursuant to the notification, only the amended version of section V of the appeal is submitted herewith.

It is requested that the Appeal Brief be amended by replacing Section V of the Appeal Brief filed November 2, 2009 with the present, corrected version of Section V.

Consideration of Appellant's Appeal Brief as amended by the present paper is respectfully requested.

No fee is believed due. The Commissioner is hereby authorized to charge any fee(s) determined to be due and/or credit any overpayments to Deposit Account No. 01-1425.

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Patent

### V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 22 is directed to a method for reducing shedding of E. coli strain O157:H7 in an animal by administering an adjuvanted vaccine composition. The vaccine composition comprises inactivated or killed whole E. coli O157:H7, aluminum hydroxide and an adjuvant. The adjuvant is an oil emulsion and comprises 1% to 3% vol/yol (v/v) of polyoxyethylene-polyoxypropylene block copolymer, 2% to 6% v/v of squalane, 0.1 % to 0.5% v/v of polyoxyethylene sorbitan monooleate, and buffered salt solution. The vaccine is administered in an effective amount by parenteral injection. The vaccine optionally includes a pharmaceutically acceptable carrier.

Support for a method for reducing shedding of E. coli strain O157:H7 in an animal by administering an adjuvanted vaccine composition of the invention is found in the specification at page 1, lines 6 to 9, and page 13, lines 20 to 22. Support for the vaccine composition comprising inactivated or killed whole E. coli O157:H7, aluminum hydroxide and an adjuvant is found in the specification at page 3, lines 2 to 5, page 4, lines 9 to 11 and page 6, lines 11 to 13. Support for the adjuvant being an oil emulsion and comprising 1% to 3% vol/vol (v/v) of polyoxyethylene-polyoxypropylene block copolymer, 2% to 6% v/v of squalane, 0.1 % to 0.5% v/v of polyoxyethylene sorbitan monooleate, and buffered salt solution is found in the specification at page 4, lines 3 to 10, and page 6, lines 4 to 10. Support for the vaccine being administered in an effective amount by parenteral injection is found in the specification at page 7, lines 18 to 26 and page 10, lines 30 to 31. Support for the vaccine optionally including a pharmaceutically acceptable carrier is found in the specification at page 6, lines 25-32 and original claim 1.

#### CONCLUSION

Applicants respectfully request consideration of the amended Appeal Brief and allowance of pending claims 22 to 24.

Respectfully submitted.

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